DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

MAR 18 2005

Mr. Mel Vanden Berg
Vice President - Quality Assurance
Proliant Health Ingredients
2425 SE Oak Tree Court
Arkeny, Iowa 50021

Dear Mr. Vanden Berg:

This is in response to your letter of February 10, 2005 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your letter states that the following statements, among others, will be made for the product ImmunoLin® : "[M]aintain LDL (bad) cholesterol within a normal and healthy range."

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. Therefore, because the claims you are making for this product represent that the product is intended to affect blood cholesterol but do not also include statements about it being intended to affect blood cholesterol that is already in the normal range, they are implied disease claims.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate a disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

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Please contact us if we may be of further assistance.

Sincerely yours,

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Kansas City District Office, Office of Compliance, HFR-SW340

Proliant
HEALTH INGREDIENTS
The Art of Service.
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MAH

February 10, 2005

Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, DC 20204

In accordance with Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, this is a letter of notification with regard to the marketing of ImmunoLin®, a dietary supplement containing immunoglobulin proteins of bovine origin.

Manufacturer: Proliant Health Ingredients
2425 SE Oak Tree Court
Ankeny, IA 50021

"Statements Made in Labeling":

> "ImmunoLin is a dietary supplement that helps maintain LDL (bad) cholesterol within a normal and healthy range."
> "ImmunoLin contains proteins that help maintain LDL (bad) cholesterol within a normal and healthy range."

To the best of my knowledge, the information contain in this notice is complete and accurate, and Proliant Health Ingredients has substantiation that the statements are truthful and not misleading.

Mel Vanden Berg
Vice President - Quality Assurance

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MVB/jk